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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/177,427	10/22/98	LUKAS	S 4804-4

HM22/0508
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EXAMINER
BERMAN, A

ART UNIT	PAPER NUMBER
1619	26

DATE MAILED: 05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/177,427	Applicant(s) LUKAS ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>21,25</u> . | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Receipt is acknowledged of the information disclosure statements filed September 20, 2000 and March 30, 2001 and the request for extension of time, request for CPA and amendment filed February 28, 2001. Claims 1-15 have been canceled. Claims 16-30 have been added and are pending.

Continued Prosecution Application

2. The request filed on February 28, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 23 is acceptable and a CPA has been established. An action on the CPA follows.

Information Disclosure Statement

3. The documents of Tasic et al. provided in the information disclosure statement filed September 20, 2000 and Deasy provided in the information disclosure statement filed March 30, 2001 have been considered on other information disclosure statements.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 16-25 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by CA 2,068,366 (366).

CA '366 discloses particles comprising a core containing at least one pharmaceutically active ingredient with a continuous coating on the core (abstract). The coating comprises about 10-80% of the formulation (page 4, lines 15-23). The particle size of the core is about 0.1 to 250 microns, more preferably about 35-125 microns (page 4, line 38 to page 5, line 4). The coating thickness is about 0.005-25 microns (page 5, lines 5-10). For paracetamol as the pharmaceutically active ingredient, see page 5, line 16. For ethyl cellulose as the coating, see page 8, lines 21-27). At page 13, lines 1-23, CA '366 teaches a process of making the particles comprising suspending or dispersing the pharmaceutically active ingredient in the coating solution and spray-drying the suspension. See also example 1 at page 17, line 30 to page 18, line 7, which teaches spray-drying a solution of ethylcellulose and paracetamol. The powder obtained exhibited taste-masking and sustained release of the paracetamol.

6. Claims 16-20, 22-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,808,411 ('411).

US '411 discloses antibiotic/polymer complexes. A suitable antibiotic for use in the complexes is 6-O-methylerythromycin (clarithromycin). See the abstract. The complexes provide slow release of the antibiotic in order to mask the bitter taste (col. 4, lines 24-27). The antibiotic/polymer complexes can be provided in a dry, solid form, preferably in the form of particles (col. 4, lines 36-38). The particle diameter of the complexes may be smaller than 297 microns, which encompasses the particle size

ranges instantly claimed. See also Example 5 at column 6 for a particle size of 60 mesh (250 microns). The complexes may be further coated with a polymer such as ethyl cellulose (col. 4, lines 57-61). Example 6 at column 6 teaches spray-drying a complex comprising clarithromycin with a coating.

7. Because neither of the references mention any limitations on the shape of the particles, the formulations of the prior art inherently encompass any suitable shape with any suitable aspect ratio. Therefore, the limitations of the aspect ratio and spherical shape of the particles as instantly claimed are not considered critical and do not render the claims patentable over the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,068,366 (366) in combination with either US 4,808,411 (411) or US 5,707,646 (646) each.

CA '366 teaches all of the limitations of the claims as stated above. CA '366 further teaches that any oral penicillins are suitable in the formulation (page 7, line 30). However, CA '366 does not specifically teach clarithromycin, spherical particles or the aspect ratio of the particles.

US '411 teaches that clarithromycin has a bitter taste and is suitable for administration in particles that contain a polymer coating in order to provide sustained release and taste-masking. See above. US '646 teaches that clarithromycin is a bitter tasting pharmaceutical that may be administered as particles containing a polymeric coating in order to provide taste masking.

It is within the skill in the art to select optimal parameters, such as the shape and aspect ratio of particles, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). All of the references obtain the same results desired by Applicants, specifically taste-masking and sustained release. Therefore, absent evidence of unexpected results, the shape and aspect ratio of the particles are not considered critical to the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the particles of CA '366 using clarithromycin as the oral penicillin as

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taught by either US '411 or US '646 in any suitable shape expecting to provide a formulation of clarithromycin that can be administered orally that exhibits acceptable taste-masking and sustained release.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4456 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
May 3, 2001

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